

**REMARKS / ARGUMENTS**

This communication responds to the Final Office Action of July 21, 2010, in which claims 1-74 are pending, and claims 1-30, 47, and 49-72 are withdrawn. Claims 31-46, 48, and 73-74 are rejected.

With this Amendment and Response, claims 31, 38, and 73 are amended, no claims are cancelled, and claim 75 is added. Thus, claims 1-75 are pending.

No new matter has been added. Claim 31 is amended to incorporate the subject matter of claim 38. Claims 38 and 73 are amended to properly depend from claim 31. Support for new claim 75 may be found throughout the specification and claims as filed, for example, Abstract, paragraphs [0010], [0014]-[0015], and [0239]-[0263], and claim 38.

Applicants have not publicly dedicated or abandoned any unclaimed subject matter. Further, the Applicants have not acquiesced to any rejections made by the Examiner in the Office action, but have merely amended claims in an effort to expedite prosecution. Applicants reserve the right to pursue prosecution of any presently or previously excluded or cancelled claim embodiments in one or more future continuation and/or divisional applications.

**I. Obviation and Withdrawal of Objections and Rejections**

Applicants acknowledge that “amendment to claim 43 obviates the objection of record.” *Office Action*, p. 3.

Applicants acknowledge the Patent Office’s statement that “amendment to the claims have obviates the objection of record.” *Id.*

Applicants acknowledge the Patent Office’s statement that “[t]he amendments to the claims . . . obviates the rejection under 35 U.S.C. 102(b) as being anticipated by O’Leary et. al.” *Id.*

Applicants appreciate and acknowledge the Patent Office’s withdrawal of the obviousness rejection based on O’Leary. *Id.* at p. 6.

Applicants appreciate and acknowledge that the Patent Office has found persuasive the argument made regarding the non-obviousness of the present claims in light of the disclosure of Landesman. *Id.*

## II. New Claim Rejections Under 35 U.S.C. §102

The Patent Office rejects claims 31, 38-40, 48, and 72 under 35 U.S.C. § 102(b) as anticipated by Landesman et al. (Calcified Tissue International, 1989).

According to the M.P.E.P., “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single . . . reference” and the reference describes the invention in as “complete detail as is contained in the . . . claim.” § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed.Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed.Cir. 1989).

The Patent Office cites Landesman for “disclos[ing] bone matrix which has been subjected to collagenase treatment” and exhibits “greater chemotaxis-inducing activity than the unmodified control.” *Office Action*, p. 5. The Patent Office concedes that “there are slight differences between the collagenase digestion method of Landesman et al and the method carried out in Example 10” and therefore “the resulting products cannot be held to inherently have the same characteristics.” *Id.*, p. 4. The Patent Office concedes that “Landesman et al cannot be held to have the same increased osteogenic activity as the bone matrix produced by the method of Example 10 . . . , and encompassed by the instant claims.” *Id.* However, in maintaining its rejection based on Landesman, the Patent Office argues that “the collagenase-treated bone matrix of Landesman et al is considered to have an increased *chemotactic* activity compared to the untreated matrices,” and therefore “Landesman et al anticipates the modified bone matrix of current claims.” *Id.* at p. 5 (*emphasis in original*).

Without agreeing with or acquiescing to the Patent Office’s rejection, and solely to advance prosecution, Applicants have amended claim 31 to recite:

[a] modified bone matrix . . . wherein the level of at least one biological activity . . . is increased relative to its level in an unmodified control bone matrix, . . . and wherein the at least one biological activity is selected from the group consisting of osteoinductive activity, osteogenic activity, and chondrogenic activity.

The recited group of biological activities does not include chemotactic activity.

Thus, because Landesman does not expressly or inherently teach each and every aspect of the currently claimed modified bone matrix, Landesman does not anticipate the current claims.

Because Landesmen does not anticipate independent claim 31, all claims depending therefrom are also not anticipated.

The Patent Office's rejection is inapposite and should be withdrawn.

### **III. New Claim Rejections Under 35 U.S.C. §112**

According to the M.P.E.P. whether a specification satisfies the enablement requirement is a fact based analysis involving the weighing of many factors:

includ[ing], but . . . not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

§ 2164.01, citing *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988)

Thus, “[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied.” M.P.E.P. § 2164.08; see for example, *In re Fisher*, 427 F.2d 833 (CCPA 1970). Moreover, the form of disclosure is not important and can be made “by specific example or broad terminology.” *Id.*, citing to *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971).

#### **A. Support For “Biological Activities” as recited in Claim 31.**

The Patent Office argues that “the specification does not provide sufficient evidence or guidance to enable one having ordinary skill in the art to produce a modified bone matrix which has an increased level of any biological activity compared to unmodified control bone matrix.” *Office Action*, p. 9.

The present claims are directed to modified bone matrix wherein at least one of the “osteoinductive activity, osteogenic activity, and chondrogenic activity” is increased relative to an unmodified bone matrix.

The Patent Office admits that “[t]he specification does provide sufficient evidence and guidance to enable one having ordinary skill in the art to produce a modified bone matrix which

has an increased osteogenic or chondrogenic activity compared to unmodified control bone matrix." *Office Action*, p. 9. The specification also provides extensive enabling support for increased osteoinductive activity. For example, at paragraph [0015], the specification clearly sets forth the nature of the claim while providing one of skill in the art extensive direction in the form of a working example: "in certain embodiments of the invention the treated bone matrix composition displays increased osteoinductive . . . activity, measured using a tissue culture assay such as that described in Example 10, as compared with the osteoinductive . . . activity of an otherwise identical untreated bone matrix composition." At paragraph [0051], the term "osteoinductive" is defined as "[a]ny material that can induce the formation of ectopic bone in the soft tissue of an animal is considered osteoinductive." Likewise, terms "osteogenic" and "chondrogenic" are also defined. See, paras. [0043] and [0050]. At paragraph [0071], the specification teaches that the biological activity of the modified bone matrix may be measured by an assay such as an alkaline phosphatase (AP) assay. The specification further directs one of skill in performing the alkaline phosphatase assay. Para. [0250]. At Example 10, cleavage of bone matrix to create modified bone matrix resulted in higher AP production. Paras. [0239]-[0263].

Thus, the specification discloses a working example directing one of skill in the art in making and using the claimed modified bone matrix having increased biological activity. This description mirrors the nature and breadth of the claims, while greatly reducing or eliminating the need for any experimentation.

The Patent Office's rejection is inapposite and should be withdrawn.

**B. Support for "Cleavage Agent . . . CNBr" As Recited in Claim 31.**

The Patent Office rejects Claim 31 for failing to provide support for CNBr.

Applicants traverse this ground for rejection.

Without admitting or acquiescing to the Examiner's position, and solely to advance prosecution, independent claim 31 is amended. Claim 31 has been amended to recite "[a] modified bone matrix comprising a bone matrix that has been exposed to collagenase to produce a modified bone matrix, wherein the level of at least one biological activity of the modified bone matrix is increased."

This ground for rejection is inapposite and should be withdrawn.

#### IV. Double Patenting

Claims 31, 38-40, 42, 43 and 48 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 73, 77, 83, and 84 of co-pending Application No. 12/140,025.

Because the present case is pending, and subject to continued prosecution which may obviate any substantive ground for obvious-type double-patenting, Applicants continue to respectfully request that the provisional rejection be held in abeyance until allowable subject matter has been found in the instant application.

#### CONCLUSION

This response is being submitted on or before November 21, 2010, with the required fee for a one-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

DORSEY & WHITNEY LLP

**Customer Number 25763**

Date: July 21, 2010

By: Kenneth E. Levitt

Kenneth E. Levitt, Reg. No. 39,747

(612) 340-2755